EXHIBIT A

Excerpts from the transcript of the July 17, 2019 deposition of Jay W. Heinecke, M.D

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Page 1
1
                 UNITED STATES DISTRICT COURT
                       DISTRICT OF NEVADA
5
6
     AMARIN PHARMA, INC., et al.,
7
8
                  Plaintiffs,
                                          )
                                             Case No.:
                                             2:16-cv-02525-MMD-NJK
                   vs.
                                             Consolidated with:
                                          )
10
                                             2:16-cv-02562-MMD-NJK
    HIKMA PHARMACEUTICALS USA INC.,
11
     et al.,
12
13
                  Defendants.
14
15
16
17
                   VIDEOTAPED DEPOSITION OF
                      JAY W. HEINECKE, M.D.
19
                    San Francisco, California
20
                    Wednesday, July 17, 2019
21
22
23
    Reported by Stenographer
    MARY J. GOFF
24
    CSR No. 13427
     Job No. 162979
25
```

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1	1490 2	1	
2		1 2	APPEARANCES:
3		3	For Plaintiffs
4	Videotaped Deposition of	4	
5	JAY W. HEINECKE, M.D., Volume I, taken on behalf of	5	COVINGTON & BURLING
6	Plaintiffs, at Winston & Strawn LLP, 101 California	6	BY: CHRISTOPHER SIPES, ESQ.
7	Street, San Francisco, California 94111, beginning	7	ERIC SONNENSCHEIN, ESQ. One City Center
8	at 8:04 a.m. and ending at 4:12 p.m., on July 17,	8	850 Tenth Street, NW
9	2019, before MARY J. GOFF, California	9	Washington, DC 20001
10	Certified Shorthand Reporter No. 13427.	10	Washington, DC 20001
11	Columba differential reporter 110. 13 127.	11	
12		12	
13		13	
14		14	For Defendants
15		15	Winston & Strawn
16		16	BY: EIMERIC REIG-PLESSIS, ESQ.
17		17	101 California Street
18		18	San Francisco, California 94111
19		19	Z
20		20	
21		21	
22		22	
23		23	
24		24	
25		25	
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3	tablets AMRN-PEXP-0001692-712	3	Clinical and Experimental, Vol 56 No. 1, 1995
4			ICOSAPENT_DFNDTS00006159-68
5	Exhibit 7 Atherosclerosis, 26 (1977)603-609 122	4	
6	AMRN-PEXP-0008180-186 Lars Carson article, On the Rise	5	Exhibit 15 Eicosapentaenoic Acid Effect on 263 Hyperlipidemia in Menopausal
7	Ears Carson article, on the ruse	6	Japanese Women by Kurabayashi, et al.
8	Exhibit 8 Article from the Journal of Clinical 134	7	ICOSAPENT_DFNDTS00006237-44
9	Lipidology, Pilot Study AMRN00621043-49	8	Exhibit 16 US Patent 8,293,728 276
10			AMRN-PEXP-000000122
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15	AMRN-PEXP-0009110-112		(JELIS) Yokoyama, et al.
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17	Oralli and Figure		Exhibit 19 Epadel Capsules 300, Approval 316 ICOSAPENT_DFNTS00008961-69
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19	docosahexaenoic acids ICOSAPENT-DFNDTS00006520-29	17	Exhibit 20 Publication No. WO 2008/004900 A1 329 ICOSAPENT DFNTS00007108-150
20	Exhibit 13 A Review of Omega-3 Ethyl Esters 236	18	ICOSAFEN1_DI'N150000/100-150
0.7	for Cardiovascular Prevention and	19	
21	Treatment of Increased Blood Triglyceride Levels by	20 21	
22	Clemens von Schacky	22	
23	·	23	
24 25		24 25	
	D 0		D 0
	Page 8		Page 9
1	San Francisco, California 10:20	1	With me is my colleague, Eric 08:04
2	July 17, 2019 10:20	2	Sonnenschein; and Joe Kennedy of Amarin 08:04
3	8:04 a.m. 10:20	3	Pharmaceuticals. 08:04
4	10:20	4	MR. REIG-PLESSIS: I'm Eimeric Reig of 08:04
5	THE VIDEOGRAPHER: Good morning. This is 08:02	5	Winston & Strawn, on behalf of the Hikma Defendants 08:04
6	the start of media labeled No. 1 of the video 08:02	6	and the witness. 08:04
7	recorded deposition of Dr. Jay W. Heinecke, in the 08:02	7	THE VIDEOGRAPHER: And has anyone joined 08:04
8	matter of Amarin Pharma, Inc., et al, versus Hikma 08:03	8	on the phone yet? 08:04
9	Pharmaceuticals USA Inc., et al., in the United 08:03	9	MR. REIG-PLESSIS: I don't think so. 08:04
10	States District Court, District of Nevada, 08:03	10	MR. SIPES: Okay. Great. 08:04
11	Case No.: 2:16-cv-02525-MMD-NJK; Consolidated 08:03	11	JAY W. HEINECKE, M.D., 08:04
12	with: 2:16-cv-02562-MMD-NJK. 08:03	12	being first duly sworn or affirmed to testify to the 08:04
13	This deposition is being held at Winston & 08:03	13	truth, the whole truth, and nothing but the truth, 08:04
14	Strawn, 101 California Street, San Francisco, 08:03	14	was examined and testified as follows: 08:04
15	California, on July 17, 2019, at approximately 08:03	15	EXAMINATION 08:04
16	8:04 a.m. 08:03	16	BY MR. SIPES: 08:04
17	My name is Marcus Majers. I'm the legal 08:03	17	Q Good morning. Thank you for coming in 08:04
18	video specialist from TSG Reporting, Inc., 08:03	18	this morning. 08:04
19	headquartered at 747 Third Avenue, New York, 08:03	19	Could you please state your name and spell 08:04
20	New York. The court reporter is Mary Goff, in 08:03	20	it for the record? 08:04
21	association with TSG Reporting. 08:03	21	A Yes. My name is Jay Walter Heinecke, 08:04
	Will all counsel present please introduce 08:04	22	HEINECKE; JAY; Walter, WALTER. 08:04
22	77 III all coulises present pieuse introduce 00.07	23	Q And where do you reside? 08:04
	themselves 08·04		
23	themselves. 08:04 MR_SIPES: Christopher Sines of Covington, 08:04		
	themselves. 08:04 MR. SIPES: Christopher Sipes of Covington 08:04 & Burling LLP, on behalf of the Plaintiff. 08:04	24	A I reside in Seattle, Washington. 08:04 Q And you are currently employed? 08:04

	Page 10		Page 11
1	A I'm currently provide by the University of 08:04	1	that fair? 08:05
2	Washington. 08:04	2	A Yes. 08:05
3	Q And what is your work address? 08:04	3	Q This is not an endurance test. If at some 08:05
4	A My work address would be the University of 08:05	4	time you need a break, let me know and we'll try to 08:05
5	Washington, 850 Republican Street, Seattle 98109. 08:05	5	endeavor to find a good breaking point for you. 08:05
6	Q Okay. Have you been deposed before? 08:05	6	A Okay. 08:05
7	A I have never been deposed as an expert 08:05	7	Q You understand that the court reporter is 08:05
8	witness. 08:05	8	taking down a transcript, so you'll need to answer 08:05
9	Q You have been deposed as a fact witness? 08:05	9	audibly with verbal responses? 08:05
10	A As a what? 08:05	10	A I do. 08:06
11	Q Have you been deposed as a fact witness? 08:05	11	Q Also, you your counsel may from time to 08:06
12	Have you ever been deposed in any capacity? 08:05	12	time object, but you'll need to answer the 08:06
13	A I have. 08:05	13	questions, if you understand them, unless you're 08:06
14	Q Okay. How many times? 08:05	14	instructed not to answer by counsel. 08:06
15	A One time. 08:05	15	Do you understand? 08:06
16	Q Okay. I will go through the rules. I 08:05	16	A I understand. 08:06
17	suspect you you know them, having been through 08:05	17	Q Is there any reason why you cannot give 08:06
18	it. 08:05	18	complete and truthful testimony today? 08:06
19	But first, you understand that you are 08:05	19	A No, not that I'm aware after. 08:06
20	under oath today and are required to answer my 08:05	20	Q Okay. And as far as you're you don't 08:06
21	questions truthfully? 08:05	21	have any medical condition or medications that might 08:06
22	A Yes. 08:05	22	interfere with your ability to answer truthfully? 08:06
23	Q If you don't understand a question, please 08:05	23	A No. 08:06
24	let me know and I will attempt to clarify it. 08:05	24	Q Let me hand to you three documents that 08:06
25	Otherwise, I will assume that you understood it; is 08:05	25	have been marked as Exhibits 1, 2, and 3 in the 08:06
	<u> </u>		
	Page 12		Page 13
1	Page 12 case. 08:06	1	Page 13 Q We can go through them one at a time, I 08:07
1 2		1 2	
	case. 08:06		Q We can go through them one at a time, I 08:07
2	case. 08:06 (Exhibit 1 was marked for identification 08:06	2	Q We can go through them one at a time, I 08:07 A Okay. 08:07
2	case. 08:06 (Exhibit 1 was marked for identification 08:06 and is attached to the transcript.) 08:06	2	Q We can go through them one at a time, I 08:07 A Okay. 08:07 Q think is easiest. 08:07
2 3 4	case. 08:06 (Exhibit 1 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 2 was marked for identification 08:06	2 3 4	Q We can go through them one at a time, I 08:07 A Okay. 08:07 Q think is easiest. 08:07 A Fine. 08:07
2 3 4 5	case. 08:06 (Exhibit 1 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 2 was marked for identification 08:06 and is attached to the transcript.) 08:06	2 3 4 5	Q We can go through them one at a time, I 08:07 A Okay. 08:07 Q think is easiest. 08:07 A Fine. 08:07 Q And Exhibit 1 is the your opening 08:07
2 3 4 5 6	case. 08:06 (Exhibit 1 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 2 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 3 was marked for identification 08:06	2 3 4 5	Q We can go through them one at a time, I 08:07 A Okay. 08:07 Q think is easiest. 08:07 A Fine. 08:07 Q And Exhibit 1 is the your opening 08:07 report 08:07
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2 3 4 5 6 7 8	case. 08:06 (Exhibit 1 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 2 was marked for identification 08:06 and is attached to the transcript.) 08:06 (Exhibit 3 was marked for identification 08:06 and is attached to the transcript.) 08:06 A Okay. 08:06	2 3 4 5 6 7 8	Q We can go through them one at a time, I 08:07 A Okay. 08:07 Q think is easiest. 08:07 A Fine. 08:07 Q And Exhibit 1 is the your opening 08:07 report 08:07 A Yes. 08:07 Q in this case, correct? 08:07
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1 Q But the the not significant increase	Page 83
2 was 2.5 percent — 09:13 3 A Yes. 09:13 3 A Yes. 09:13 4 Q — over placebo in the high triglyceride op:13 5 group, correct; and it was 49.2 percent? 09:14 6 A Yes. 09:14 7 Q So it was many times larger in the very 09:14 8 high triglyceride group, correct? 09:14 9 A Correct. 09:14 10 Q Okay. So a person of ordinary skill in 09:14 11 the art is going to recognize that the fibrates 09:14 12 produced a — a much larger and statistically 09:14 13 significant increase in LDL cholesterol in the very 09:14 14 high triglyceride patient population, 09:14 15 show even a statistically significant hange in the 09:14 16 high triglyceride pop — patient population, 09:14 17 correct? 09:14 18 A In this particular study, correct. 09:14 19 Q Okay. And the clinical study in the 09:14 110 Q Okay And the clinical study in the 09:14 121 TRICOR labeling would have been a clinical study 09:14 122 A Yes. 09:14 123 Q — reviewed by FDA — 09:14 124 A Yes. 09:14 125 Q — correct? 09:14 126 A Yes. 09:14 127 Order (Policy of the produced a — 09:14 13 A Yes, 09:14 14 high triglyceride pop — patient population, 09:14 15 influence that conclusion 09:16 16 Q (BY MR. SIPES) And what other factors on of ordinary skill in the art in 2008 would understand from the 2004 TRICOR labeling that patients that high triglycerides, but also had high LDL-C cholesterol, saw a decrease in LDL-C from TRICOR was a decrease in LDL-	09:14
3 A Yes. 4 Q - over placebo in the high triglyceride op:13 5 group, correct; and it was 49.2 percent? 6 A Yes. 6 Q So it was many times larger in the very op:14 7 Q So it was many times larger in the very op:14 8 high triglyceride group, correct? 9 A Correct. 9 Q Okay. So a person of ordinary skill in 09:14 12 produced a a much larger and statistically op:14 13 significant increase in LDL cholesterol in the very op:14 14 high triglyceride patient population and did not op:14 15 show even a statistically significant change in the op:14 16 high triglyceride patient population and did not op:14 17 correct? 18 A In this particular study, correct. 19 Q Okay. And the clinical study in the op:14 18 Q Okay. And the clinical study in the op:14 19 Q Okay. And the clinical study in the op:14 10 Q Okay. And the clinical study in the op:14 11 that was op:14 12 A Yes. 19 Q - reviewed by FDA op:14 12 A Yes. 19 Q - reviewed by FDA op:14 10 MR. REIG-PLESSIS: Objection to form. Page 84 1 its triglyceride level, correct? 19 09:16 2 Q (BY MR. SIPES) And what other factors op:16 2 MR. REIG-PLESSIS: Objection to form. Page 84 1 its triglyceride level, correct? 19 09:16 2 Q (BY MR. SIPES) And what other factors op:16 2 MR. REIG-PLESSIS: Objection to form. Page 84 1 its triglyceride level, correct? 19 09:16 2 Q (BY MR. SIPES) And what other factors op:16 2 Q (BY MR. SIPES) And what other factors op:16 3 A Yeah, that's very specific. I think there op:16 4 could be a number of other factors that could op:16 5 influence that conclusion. 19 09:16 20 Q And would a person of ordinary skill in op:16 21 the art believe that the patients with insiced op:16 22 dyslipidemia likely had a different underlying op:16 23 disorder than the patients with high triglycerides? 24 A Yes, that would be likely. 25 Q Okay. And similarly, would a person of op:16 26 Q Okay. And similarly, would a person of op:16 27 op:16 o	07.14
4 Q - over placebo in the high triglyceride	09:14
group, correct; and it was 49.2 percent? A Yes. O9:14 A Yes. O9:15 A Yes. O9:14 A Yes. O9:15 A Yes. O9:14 A Yes. A Yes. O9:14 A Yes. A Yes. O9:15 A Yes. O9:14 A Yes. A Yes. O9:16 A Yes. O9:14 A Yes. A Yes, And would a person of ordinary skill in O9:16 B A Yes, And would a person of ordinary skill in O9:16 C A Yes. O9:14 C A Yes. O9:16 C A Yes. O9:14 C A Yes. O9:16 C A Yes. O9:18 C A Yes. O9:18 C A Yes. O9:18 C A Yes. O9:19 C A Yes. O9:19	09:14
A Yes. 09:14 New A Yes. 09:15 New A Yes. 09:15 New A Yes. 09:15 New A Yes. 09:15 New A Yes. 09:16 New A Yes. 09:16	
Page 84 I is triglyceride would have been a clinical study that was	
high triglyceride group, correct? 09:14 A Correct. 09:14 Q Okay. So a person of ordinary skill in 09:14 the art is going to recognize that the fibrates 09:14 liph triglyceride are in LDL cholesterol in the very 09:14 high triglyceride portent population and did not 09:14 high triglyceride portent population and did not 09:14 high triglyceride pop patient population, 09:14 liph triglyceride pop patient population, 09:	,
9 A Correct. 10 Q Okay. So a person of ordinary skill in 09:14 11 the art is going to recognize that the fibrates 09:14 12 produced aa much larger and statistically 09:14 13 significant increase in LDL cholesterol in the very 09:14 14 high triglyceride patient population and did not 09:14 15 show even a statistically significant change in the 09:14 16 high triglyceride pop patient population, 09:14 17 correct? 09:14 18 A In this particular study, correct. 09:14 19 Q Okay. And the clinical study in the 09:14 20 TRICOR labeling would have been a clinical study 09:14 21 that was 09:14 22 A Yes. 09:14 23 Q reviewed by FDA 09:14 24 A Yes. 09:14 25 Q correct? 09:14 26 Triglyceride level, correct? 09:14 27 its triglyceride level, correct? 09:14 28 A Yes. 09:14 29 TRICOR labeling would have been a clinical study 09:14 20 TRICOR labeling would have been a clinical study 09:14 21 that was 09:14 22 A Yes. 09:14 23 Q reviewed by FDA 09:14 24 A Yes. 09:14 25 Q correct? 09:14 26 TRICOR labeling would have been a clinical study 09:14 27 that was 09:14 28 A Yes. 09:14 29 C reviewed by FDA 09:14 20 G reviewed by FDA 09:14 21 tis triglyceride level, correct? 09:14 22 D correct? 09:14 23 Q reviewed by FDA 09:14 24 A Yes. 09:14 25 Q correct? 09:14 26 TRICOR labeling would have been a clinical study 09:14 27 correct? 09:14 28 A Yes. 09:14 29 Q reviewed by FDA 09:14 20 G reviewed by FDA 09:14 21 distriglyceride level, correct? 09:16 22 A Yes. 09:14 23 Q reviewed by FDA 09:16 24 A Yes. 09:16 25 Q correct? 09:16 26 Q (BY MR. SIPES) And what other factors 09:16 27 could be a number of other factors that could 09:16 28 A Well, the underlying genetic disorder, for 09:16 29 example. 10 Q And would a person of ordinary skill in 09:16 20 Q (BY MR. SIPES) And what other factors 09:16 21 dyslipidemia likely had a different underlying 09:16 22 MR. REIG-PLESSIS: That's Exhibit 2. 05 23 A Yes. 11 24 A Yes, that would be likely. 09:16 25 Q Okay. And similarly, would a	09:15
the art is going to recognize that the fibrates	09:15
the art is going to recognize that the fibrates 12 produced a a much larger and statistically 13 significant increase in LDL cholesterol in the very 14 high triglyceride patient population and did not 15 show even a statistically significant change in the 16 high triglyceride patient population 17 correct? 18 A In this particular study, correct. 19 Q Okay. And the clinical study in the 19 Q Okay. And the clinical study in the 10 Q Oy:14 11 but also had high LDL-C, actually saw a decrease 11 placebo from fibrates, correct? 12 Oy:14 13 placebo from fibrates, correct? 14 MR. REIG-PLESSIS: Objection to form. 15 A Yeah, can you restate that, please? 16 Q Okay. And the clinical study in the 17 ordinary skill in the art in 2008 would understand from the 2004 TRICOR labeling that patients that 18 high triglycerides, but also had high LDL-C 19 correct? 10 Oy:14 10 Cy Okay. And the clinical study 10 Oy:14 12	, 09:15
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8 A Well, the underlying genetic disorder, for 09:16 9 example. 09:16 10 Q And would a person of ordinary skill in 09:16 11 the art believe that the patients with mixed 09:16 12 dyslipidemia likely had a different underlying 09:16 13 disorder than the patients with high triglycerides? 09:16 14 A Yes, that would be likely. 09:16 15 Q Okay. And similarly, would a person of 09:16 8 record at 9:30 a.m. 09:29 9 Q (BY MR. SIPES) Dr. Heinecke, let me ask 10 you to turn to paragraph 137 of your rebuttal 09 11 report. 09:29 12 MR. REIG-PLESSIS: That's Exhibit 2. 09 13 A Yes. 09:29 14 Q (BY MR. SIPES) In paragraph 137, you 09:16 15 state, Fibrates, niacin, Lovaza, EPANOVA, and Omtro	09:29
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· · · · · · · · · · · · · · · · · · ·	09:29
ordinary skill in the art in 2008 understand that 09:16 lb were (and still are) all FDA approved to reduce 0	yg 09:29
I	9:29
patients with very high triglycerides likely had a 09:16 triglycerides, including in the claimed patient 09:	30
	09:30
mixed dyslipidemia? 09:16 per deciliter or higher, correct? 09:30	
A Yes, I believe that's correct. 09:16 20 A Yes. 09:30	
Q Okay. 09:16 21 Q And that list of fibrates, niacin, Lovaza, 09:3	
THE DEPONENET: Can we take a restroom 09:16 22 EPANOVA, and Omtryg, along with VASCEPA, is the	ne full 09:30
	9:30
MR. SIPES: Why don't we take a break. 09:16 24 very high triglycerides, correct? 09:30	
A That sounds good. Thank you. 09:16 25 A I I don't know the answer to that. 09:30	

	Page 86		Page 87
,			
1	Q Okay. Are you aware of any drug approved 09:30	1	Q Is it your understanding that EPANOVA was 09:31
2	by FDA to treat very high triglycerides, other than 09:30	2	approved by March of 2008? 09:31
4	fibrates, niacin, Lovaza Lovaza, EPANOVA, Omtryg 09:30	4	MR. REIG-PLESSIS: Objection to form. 09:31 A I can't answer that question. 09:31
5	and VASCEPA? 09:30	5	-
6	A No. 09:30 Q Now, you state that those that, 09:30	6	Q (BY MR. SIPES) Now, it's not your 09:31
7	Fibrates, niacin, Lovaza, EPANOVA, and Omtryg were 09:30	7	testimony sitting here today that EPANOVA is part of 09:31 the prior art, correct? 09:31
8	all FDA approved to reduce triglycerides, including 09:30	8	the prior art, correct? 09:31 A Could you could you define what you 09:31
9	in the claimed patient population with baseline 09:30	9	mean by "part of the prior art"? 09:31
10	levels of 500 milligrams per deciliter or higher. 09:30	10	Q Okay. Why don't we in your opening 09:32
11	Do you see that? 09:31	11	report 09:32
12	A Yes. 09:31	12	A Yes. 09:32
13	Q When you say "were," what time frame are 09:31	13	Q on paragraph 18 09:32
14	you talking about? 09:31	14	MR. REIG-PLESSIS: It's Exhibit 1. 09:32
15	A I know that during my time of taking care 09:31	15	A Yes. 09:32
16	of patients with high triglycerides, that niacin was 09:31	16	Q (BY MR. SIPES) Exhibit 1 09:32
17	approved for that, and fibrates (phonetic) were 09:31	17	A Yes. Thank you. 09:32
18	approved. 09:31	18	Q you note that you have been informed by 09:32
19	I don't know the exact dates for the other 09:31	19	counsel that March of 2008 is the date claimed for 09:32
20	drugs. 09:31	20	conception of the claimed inventions, correct? 09:32
21	Q Okay. Is it your 09:31	21	A Where is that written 09:32
22	A You mentioned 09:31	22	Q It's 09:32
23	Q I'm sorry. I didn't want to cut you 09:31	23	A again? 09:32
24	off. Would 09:31	24	Q actually at the top of page 8. It's 09:32
25	A Yeah. No. Excuse me. 09:31	25	the one sentence in in paragraph 18 of your 09:32
	Page 88		Page 89
1	opening report. Paragraph 18. 09:32	1	prior to March of 2008? 09:33
2	A 18. Okay. Yes. 09:32	2	A I'm trying to remember here. Well, since 09:33
3	Q So you understand and you don't dispute 09:32	3	I can't claim that I know the exact date, I would 09:34
4	the March of 2008 conception date for the inventions 09:32	4	have to agree with that. 09:34
5	at issue in this case, correct? 09:32	5	Q And you do not rely on EPANOVA for 09:34
6	A I do not. 09:33	6	purposes of your opinions on obviousness in this 09:34
7	Q All right. So is it your understanding 09:33	7	case, correct? 09:34
8	that for purposes of evaluating prior art, the 09:33	8	A If I knew the specific date of approval 09:34
9	critical date is March 2008? 09:33	9	for the EPANOVA, I could answer that correctly. 09:34
10	A Yes, it is. 09:33	10	Q Well, do you recall that you you used 09:34
11	Q Okay. So going back to the list of 09:33	11	two different obviousness combinations in your 09:34
12	medications for very high triglycerides that you 09:33	12	opinions? 09:34
13	have in your rebuttal report 09:33	13	A Yes. 09:34
14 15	A Yes. 09:33	14 15	Q And one involved the drug Lovaza? 09:34
16	Q in paragraph 137, it is not your 09:33	16	A Yes. 09:34
17	testimony is it your testimony that EPANOVA was 09:33	17	Q And the other involved the drug Epadel? 09:34
18	known in the art prior to March of 2008? 09:33	18	A Yes. 09:34
19	A I can't recall the specific date that that 09:33 was approved. 09:33	19	Q And EPANOVA is neither Epadel, nor Lovaza, 09:34 correct? 09:34
20	was approved. 09:33 Q Okay. So 09:33	20	A Correct. 09:34 A Correct. 09:34
21	A I would have to do further research 09:33	21	Q Okay. So to the best of your 09:34
22	Q Okay. 09:33	22	recollection, are you relying on EPANOVA in your 09:34
23	A on that point. 09:33	23	obviousness opinions in this case? 09:34
24	Q So sitting here today, you're not prepared 09:33	24	MR. REIG-PLESSIS: Objection to form. Do 09:34
25	to to testify that EPANOVA was known in the art 09:33	25	you mean objective indicia or premium fascia? 09:34
			, p

	Page 90		Page 91
1	Q (BY MR. SIPES) In in your opening 09:35	1	obviousness? 09:36
2	report where you opined on the obviousness of the 09:35	2	A Yes. 09:36
3	invention, did you rely on EPANOVA in forming your 09:35	3	Q Okay. Do you okay. 09:36
4	opinions? 09:35	4	Do you recall sitting here today whether 09:36
5	A Since I can't remember the specific date, 09:35	5	or not, in forming your opinion of obviousness that 09:36
6	I would have to do further research on that question 09:35	6	you expressed in your opening report, you relied on 09:36
7	to answer that. 09:35	7	Omtryg as part of the prior art? 09:36
8	Q Okay. And similarly, sitting here today, 09:35	8	A You would have to refer me to the specific 09:36
9	is it your opinion that Omtryg is prior art? 09:35	9	point where I do that. 09:36
10	A Again, I don't remember the specific date 09:35	10	Q Okay. I I don't find it in your 09:36
11	for that, and so I would have to research that 09:35	11	opening report. But I'm not the master of your 09:36
12	further in order to answer the question. 09:35	12	opinions, which 09:36
13	Q All right. And do you understand that 09:35	13	A Yeah. 09:36
14	Omtryg is neither Lovaza, nor Epadel? 09:35	14	Q is why I asked. 09:36
15	A Yes. 09:35	15	A Okay. 09:36
16	Q And you sitting here today, you're not 09:35	16	Q So I take it sitting here today, you do 09:36
17	prepared to answer one way or the other as to 09:35	17	not recall relying on Omtryg in forming your 09:36
18	whether or not, in your opinions of obviousness 09:35	18	opinions of obviousness that you expressed in your 09:36
19	expressed in your opening report, you rely upon 09:35	19	opening report? 09:36
20	Omtryg? 09:35	20	A I do not recall that. 09:36
21	MR. REIG-PLESSIS: Objection to form. 09:35	21	Q Okay. So let's turn to your opening 09:36
22	A Could you be more specific about exactly 09:35	22	report, paragraph 18. 09:36
23	what you are referring to? 09:35	23	A Paragraph 18. 09:36
24	Q (BY MR. SIPES) You you recall in your 09:35	24	Q 18, yeah. You state, I have been asked by 09:36
25	opening report, putting together opinions on 09:35	25	counsel to offer my opinions regarding the 09:37
	Page 92		Page 93
1	obviousness of the asserted claims from the point of 09:37	1	understanding of what these concepts meant. 09:38
2	view of a person of ordinary skill in the art. 09:37	2	Q You in your opening report, you do not 09:38
3	Do you see that? 09:37	3	express any opinions concerning the legal defense of 09:38
4	A Yes. 09:37	4	"anticipation," correct? 09:38
5 6	Q And the counsel you referred to there 09:37	5	A I don't know what that means. Could you 09:38
7	is is defendants' counsel, I take it, correct? 09:37	6	redefine that question, please? 09:38
8	A Yes. 09:37	7 8	Q I you are do you have an 09:38
9	Q And as you note in paragraph 25, you are 09:37	9	understanding of the legal defense of 09:38
10	not a lawyer, correct? 09:37 A Correct. 09:37	10	"anticipation"? 09:38
11	Q So you relied upon defendants' counsel's 09:37	11	A Of anticipation? I'm not recalling 09:38 anything about anticipation. 09:38
12	instructions regarding the legal standards for 09:37	12	anything about anticipation. 09:38 Q Okay. So 09:38
13	obviousness, correct? 09:37	13	A I would have to do further research on 09:38
14	A Yes, in consultation with the lawyers. 09:37	14	Q Okay. 09:38
15	Q Right. And the the legal standards 09:37	15	A that point. 09:38
16	that you applied in formulating your opinions on 09:37	16	Q So to the best of your recollection, you 09:38
17	obviousness are set forth in paragraphs 26 to 31 of 09:37	17	are not offering an opinion that the asserted claims 09:38
18	your opening report, correct? 09:37	18	are invalid for anticipation, correct? 09:38
19	A Yes. 09:37	19	A Could you define what you mean by "for 09:38
20	Q And the legal standard you used is the 09:37	20	anticipation"? 09:38
21	legal standard that you set forth from counsel; you 09:37	21	Q Well, I would like to ask the question 09:38
22	didn't rely on your own independent understanding of 09:37	22	here. And if you don't understand anticipation, 09:39
23	obviousness, correct? 09:38	23	that's fine. 09:39
1 1		l	
24	A I I consulted with counsel, taking 09:38	24	Do you find that you can't answer the 09:39
	A I I consulted with counsel, taking 09:38 advantage of their expertise, to provide my 09:38	24 25	Do you find that you can't answer the 09:39 question, whether or not you're offering an opinion 09:39

	Page 270	Page 271
1	Q (BY MR. SIPES) Can 02:04	1 say that again. 02:05
2	A Do you 02:04	² Q (BY MR. SIPES) Is it your testimony that 02:05
3	Q How would a person of ordinary skill in 02:04	from Kurabayashi, the patients who received EPA on 02:05
4	the art determine the effect of EPA alone on LDL 02:04	top of estriol, saw greater reductions in LDL-C than 02:05
5	cholesterol, given the results in Kurabayashi? 02:04	5 the control group that received estriol alone? 02:05
6	A Well, what you can conclude in this study 02:04	6 MR. REIG-PLESSIS: Same objection. 02:05
7	is that in a patient treated with estriol, that EPA 02:04	7 A I think what we can conclude is that both 02:05
8	intervention lowers the LDL cholesterol relative to 02:04	8 groups saw a significant decrease in LDL 02:05
9	a person who is taking estriol that didn't get the 02:04	9 cholesterol. 02:05
10	EPA. 02:04	Q (BY MR. SIPES) And would the conclusion be 02:05
11	So in other words, this is for this 02:04	from that that the estriol was decreasing the LDL 02:05
12	specific population where both groups were treated 02:04	12 cholesterol? 02:05
13	with estriol, EPA lowers the LDL cholesterol in 02:04	13 A Not necessarily. And I have noticed in 02:05
14	that in that particular 02:04	reviewing the papers for this that a lot of the 02:05
15	Q And 02:04	studies, the LDL cholesterol levels tend to go down 02:05
16	A group. 02:04	16 over time. 02:05
17	Q and that's what I'm trying 02:04	That was observed in JELIS as well. And I 02:05
18	to understand so and I don't understand is 02:04	have noticed that in many of the other studies. So 02:05
19	it your testimony that the data in Kurabayashi 02:04	there's there are other factors that can be 02:05
20	suggests that the group that received EPA on top of 02:04	affecting LDL cholesterol in this study. 02:06
21	estriol, saw greater reductions in LDL-C than the 02:04	Q But but it's fair to say from the 02:06
22	patients who only received estriol? 02:05	results presented in Kurabayashi that EPA did not, 02:06
23	MR. REIG-PLESSIS: Objection to form; 02:05	in a statistically significant way, reduce LDL-C 02:06
24	mischaracterizes. 02:05	cholesterol compared to control? 02:06
25	A Yeah, I'm sorry. You're going to have to 02:05	A Okay. I'm having to look at the figure 02:06
	Page 272	Page 273
1	legend here, because I think this is a fairly 02:06	1 A for a minute? Okay. 02:07
		A 101 a minute: Okay. 02.07
2	technical point. 02:06	This is the overall population, I believe, 02:08
3	technical point. 02:06 Yes, okay, I think that's reasonable 02:06	_ ·
		This is the overall population, I believe, 02:08
3	Yes, okay, I think that's reasonable 02:06	This is the overall population, I believe, 02:08 in this particular study. 02:08
3	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08
3 4 5	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08
3 4 5 6	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08
3 4 5 6 7	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08
3 4 5 6 7 8	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, correct? 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08
3 4 5 6 7 8	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07 A I think the correct interpretation is 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08 Q So Kurabayashi was not conducted in a 02:08
3 4 5 6 7 8 9 10 11	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08
3 4 5 6 7 8 9 10 11 12 13	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07 A I think the correct interpretation is 02:07 there's no statistical difference between the two 02:07 groups. 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 the deciliter. 02:08 Q So Kurabayashi was not conducted in a 02:08 hypertriglyceridemic patient population? 02:08 A No. 02:08
3 4 5 6 7 8 9 10 11 12 13 14	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07 A I think the correct interpretation is 02:07 there's no statistical difference between the two 02:07 groups. 02:07 Q (BY MR. SIPES) Right. The which is to 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08 Q So Kurabayashi was not conducted in a 02:08 hypertriglyceridemic patient population? 02:08 A No. 02:08 Q If you'll turn to page 523, the right-hand 02:08
3 4 5 6 7 8 9 10 11 12 13 14 15	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07 A I think the correct interpretation is 02:07 there's no statistical difference between the two 02:07 groups. 02:07 Q (BY MR. SIPES) Right. The which is to 02:07 say the addition of EPA to estriol did not make any 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08 Q So Kurabayashi was not conducted in a 02:08 hypertriglyceridemic patient population? 02:08 A No. 02:08 Q If you'll turn to page 523, the right-hand 02:08 column 02:09
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Yes, okay, I think that's reasonable 02:06 conclusion. It looks like there were similar 02:06 reductions in LDL cholesterol in both groups. 02:06 Q Right. Numerically, estriol alone reduced 02:06 LDL-C to a greater extent than estriol plus EPA, 02:06 correct? 02:07 A Well 02:07 MR. REIG-PLESSIS: Objection to form. 02:07 A I think the correct interpretation is 02:07 there's no statistical difference between the two 02:07 groups. 02:07 Q (BY MR. SIPES) Right. The which is to 02:07 say the addition of EPA to estriol did not make any 02:07 statistically significant difference on LDL-C? 02:07 A I think it would be correct to say that in 02:07 this particular study in these patients, yes. 02:07 Q And the baseline triglycerides in the 02:07 Kurabayashi study 02:07 A I just want to some of these studies 02:07	This is the overall population, I believe, 02:08 in this particular study. 02:08 Q The the baseline triglycerides in 02:08 Kurabayashi was 135.6 milligrams per deciliter for 02:08 the EPA group, correct? 02:08 A Yes. 02:08 Q So those are normal triglyceride levels? 02:08 A They're less than 150 milligrams per 02:08 deciliter. 02:08 Q So Kurabayashi was not conducted in a 02:08 hypertriglyceridemic patient population? 02:08 A No. 02:08 A No. 02:08 Q If you'll turn to page 523, the right-hand 02:08 column 02:09 A Yes. 02:09 A Yes. 02:09 This is the overall population, I believe, 02:08 a Yes. 02:09 This is the overall population of 02:09 triglyceride levels was 10 percent, 2 of 20, and 02:09 To you see that? 02:09 Do you see that? 02:09
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	Page 274	Page 275
1	Q Yes. 02:09	Q (BY MR. SIPES) or what what response 02:10
2	A for me? 02:09	would be considered acceptable? 02:10
3	Q There's a reference to, The proportion of 02:09	³ MR. REIG-PLESSIS: Same objection. 02:10
4	cases showing improvement of triglyceride levels was 02:09	4 A I think, again, it's a very broad 02:11
5	10 percent, 2 of 20, and 55 percent, 11 of, 20 02:09	5 question. And I think that you would have to define 02:11
6	respectively. 02:09	6 more carefully what the clinical population was. 02:11
7	A Okay. Let me just review this. Yes. 02:09	You would have to give me additional 02:11
8	Q So at least for those patients that 02:10	8 information about what exact circumstances you're 02:11
9	continued to the end of the study, 45 percent of 02:10	g talking about. Are these diabetics? Nondiabetics? 02:11
10	them that were on EPA plus estriol did not see 02:10	People with heart disease? People without heart 02:11
11	improvements in triglyceride levels, correct? 02:10	11 disease? 02:11
12	A According to the criteria, they don't 02:10	12 I think there's a lot of variables in that 02:11
13	really define here what they mean by "improvement in 02:10	13 equation. $02:11$
14	triglyceride levels," and so I think that makes that 02:10	MR. SIPES: I think this would be a good 02:11
15	statement somewhat ambiguous. 02:10	time for, among other things, a break. 02:11
16	Q So would a person of ordinary skill in the 02:10	THE VIDEOGRAPHER: This marks the end of 02:11
17	art in 2008 be able to understand that statement? 02:10	media file labeled No. 5. Off the record at 02:11
18	A I think they would say there's appears 02:10	18 2:12 p.m. 02:11
19	to be a difference between the two groups, but we 02:10	19 (A break was taken from 2:12 p.m. to 02:11
20	don't know exactly what that means because they 02:10	20 2:27 p.m.) 02:11
21	don't define what they're talking about. 02:10	2.27 p.iii.) 02.11 21 THE VIDEOGRAPHER: This marks the 02:25
22	Q For purposes of developing a treatment for 02:10	beginning of media file labeled No. 6. Back on the 02:25
23	very high triglycerides, what response rate would be 02:10	23 record 2:27 p.m. 02:25
24	desirable in the TG-lowering agent 02:10	24 Q (BY MR. SIPES) I'm going to hand you 02:26
25	MR. REIG-PLESSIS: Objection to form. 02:10	25 Exhibit 16. 02:26
23	MR. REIO-FLESSIS. Objection to form. 02.10	-5 Exhibit 10. 02.20
	Page 276	Page 277
1	Page 276 (Exhibit 16 was marked for identification 02:26	Page 277 Q Why, in your opinion, would a person of 02:27
1 2		
	(Exhibit 16 was marked for identification 02:26	Q Why, in your opinion, would a person of 02:27
2	(Exhibit 16 was marked for identification 02:26 and is attached to the transcript.) 02:26	Q Why, in your opinion, would a person of 02:27 ordinary skill in the art, for purposes of the 02:27
2	(Exhibit 16 was marked for identification 02:26 and is attached to the transcript.) 02:26 Q (BY MR. SIPES) Do you recognize Exhibit 16 02:26	Q Why, in your opinion, would a person of 02:27 ordinary skill in the art, for purposes of the 02:27 asserted patents in this case, have had a high level 02:27
2 3 4	(Exhibit 16 was marked for identification 02:26 and is attached to the transcript.) 02:26 Q (BY MR. SIPES) Do you recognize Exhibit 16 02:26 as U.S. Patent 8,293,728 that is at issue in this 02:26	Q Why, in your opinion, would a person of 02:27 ordinary skill in the art, for purposes of the 02:27 asserted patents in this case, have had a high level 02:27 of skill? 02:27
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	Page 278		Page 279
1	Q (BY MR. SIPES) All right. And what sort 02:28	1	They would have to have a detailed familiarity with 02:29
2	of knowledge would be required to evaluate the 02:28	2	the literature, and they would have to have some 02:29
3	evidence supporting the claims of the patents? 02:28	3	basic knowledge of pharmacology and biochemistry. 02:29
4	A Well, I think we outline it here. I would 02:28	4	Q And when you say to have "practical 02:29
5	probably pretty much stick with what the definition 02:28	5	experience in the field," what if somebody wasn't 02:29
6	here is, as 02:28	6	a medical doctor, that experience would not involve 02:29
7	Q And 02:28	7	treating patients, correct? 02:30
8	A as outlined in paragraph 25. 02:28	8	A Well, that would not involve prescribing 02:30
9	Q Okay. So that would require a knowledge 02:28	9	treatment for patients. 02:30
10	of of lipid biochemistry, correct? 02:29	10	Q Okay. 02:30
11	MR. REIG-PLESSIS: Objection to form; 02:29	11	A So for example, let's just imagine a Ph.D. 02:30
12	mischaracterizes. 02:29	12	They might not be able to write a prescription for 02:30
13	A Yeah, I I think the way this is meant 02:29	13	treating a patient, but I know Ph.D.s in the field 02:30
14	to explain it is is there could be different 02:29	14	who are extremely knowledgeable about many, many 02:30
15	areas within this context in this definition. 02:29	15	different aspects of of this area and would be 02:30
16	You wouldn't necessarily have to have every single 02:29	16	capable of making a very well-informed judgment. 02:30
17	one of these things. 02:29	17	Q And would a person with a Ph.D. evaluating 02:30
18	Q (BY MR. SIPES) Do you believe that you 02:29	18	the evidence supporting the invention, consult with 02:30
19	would need a medical degree? 02:29	19	a physician or other medical doctor? 02:30
20	A I do not. 02:29	20	A Not necessarily. I think, again, it 02:30
21	Q Okay. If if a person didn't have a 02:29	21	depends on your experience. 02:30
22	medical degree, what would they need to evaluate the 02:29	22	And as I'm learning in this this 02:30
23	evidence in the patent? 02:29	23	session right here with you guys, as well as my 02:30
24	A I think they would have to have extensive 02:29	24	interactions with my team, lawyers can have a very 02:30
25	experience in the lipid field, practical experience. 02:29	25	good knowledge of what's going on in this area 02:30
	Page 280		Page 281
1	because they're extremely familiar with the 02:30	1	And since we're measuring so many 02:32
2	literature and they know a lot of the wrinkles 02:31	2	different things in so many different people, trying 02:32
3	relevant to it. 02:31	3	to interpret that data would require someone with 02:32
4	So I think it's really a matter of what 02:31	4	biostatistical expertise. And for example, we get 02:32
5	exactly their knowledge is. 02:31	5	that kind of expertise when we need it. 02:32
6	Q Okay. But but you're not suggesting a 02:31	6	On the other hand, if you're trying to 02:32
7	person of ordinary skill in the art would need 02:31	7	interpret many clinical studies, I think that you 02:32
8	excess to a lawyer, I take it? 02:31		
	excess to a law yel, I take it! 02.31	8	don't necessarily need a strong biostatistical 02:32
9	• '	9	
9 10	A No. No. 02:31		background. And even just taking it at more or less 02:32
	A No. No. 02:31 Q Yeah. Okay. You don't include within the 02:31	9	background. And even just taking it at more or less 02:32 face value, the p-values. And assuming that they 02:32
10	A No. No. 02:31 Q Yeah. Okay. You don't include within the 02:31 skill set of the of the team to which a person of 02:31	9 10	background. And even just taking it at more or less 02:32 face value, the p-values. And assuming that they 02:32 have a reasonable understanding of of statistics, 02:32
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10 11 12 13 14 15 16 17 18 19 20 21	A No. No. 02:31 Q Yeah. Okay. You don't include within the 02:31 skill set of the of the team to which a person of 02:31 skill would have access, a biostatistician, I take 02:31 it? 02:31 MR. REIG-PLESSIS: Objection to form. 02:31 A I think that would depend on the 02:31 particular circumstances. And I really trying to 02:31 specify every single thing that you need to 02:31 understand these things depends on the precise 02:31 circumstances of what's being evaluated and what's 02:31 involved. 02:31 So in some circumstances you you might 02:31 need to have a very detailed evaluation of 02:31 biostatistics. And for example, in my area one 02:31	9 10 11 12 13 14 15 16 17 18 19 20 21	background. And even just taking it at more or less 02:32 face value, the p-values. And assuming that they 02:32 have a reasonable understanding of of statistics, 02:32 what a p-value test is, what a what some of the 02:32 standard tests are, that might be adequate. So it 02:32 very much depends on the exact on the exact 02:32 very much depends on the exact on the exact 02:32 Q Okay. 02:32 Q Okay. 02:32 A I think it's a it's a complicated area. 02:32 Q The patent describes a a clinical study 02:32 of 4 grams of EPA, correct, in Column 13 02:32 MR. REIG-PLESSIS: Objection to form. 02:32 Q (BY MR. SIPES) the the patent the 02:32 '728 Patent? 02:32 A I'm sorry? Where is that? 02:32
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	Page 282	Page	283
1	Q 16. 02:33	1 Q pure ester? 02:33	
2	A right in front of me. And correct me 02:33	2 A yeah, pure. 9 greater than 02:34	
3	if I'm wrong here, but that would be under the 02:33	³ 96 percent pure EPA and ester of that form of the	02:24
4	claims? 02:33	the 02:34	02.34
5	Q No. No. No. Column 13, the example. 02:33	5 O And that 02:34	
6	A Okay. Please restate the question. 02:33	6 A fatty acid. 02:34	
7	Q The the example describes a 02:33	7 Q and the and what the patent is 02:34	4
8	placebo-controlled, randomized, double-blind 12-week 02:33	Q and the and what the patent is 02.3	02:34
9	study with open-label extension conducted on EPA, 02:33		02:34
10	correct? 02:33	levels of 500 and above, correct 02:34	
11	MR. REIG-PLESSIS: Objection to form; 02:33	MR. REIG-PLESSIS: Objection to form.	02:34
12	mischaracterizes. 02:33		02:34
13	A I I think I would have to go with what 02:33	deciliter above, correct? 02:34	02.0.
14	the text says. It says a placebo a multicenter 02:33		02:34
15	placebo it says what it says. I would go with 02:33	A Well, I can quote what it says, With 02:	
16	the 02:33	1)2:34
17	Q (BY MR. SIPES) Right. 02:33		2:34
18	A text there. 02:33		2:34
19	Q And "AMR101," do you understand the 02:33		2:34
20	reference to "AMR101 in '728 Patent? 02:33	20 liter. 02:34	
21	A I do. 02:33	Q (BY MR. SIPES) So would a person of	02:34
22	Q And what is AMR101? 02:33	ordinary skill in the art in light of the study 02:3	34
23	A EPA 02:33	described there, do you believe that would require	02:34
24	Q That that's 02:33	consultation with a biostatistician to interpret the 0	2:34
25	A ester 02:33	results of that study? 02:34	
	Page 284	Page	285
			203
1	MR. REIG-PLESSIS: Objection to form and 02:34	statistical significance does not necessarily mean	02:36
1 2	as to "results." 02:34	it's clinically significant. Right. 02:36	
2	as to "results." 02:34 A I mean, there's a lot of things that are 02:35	 it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 	02:36 2:36
2 3 4	as to "results." 02:34 A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35	 it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and 	02:36 2:36 02:36
2 3 4 5	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35	 it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. 	02:36 2:36 02:36 02:36
2 3 4 5	as to "results." 02:34 A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35	 it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical 	02:36 2:36 02:36 02:36 02:36
2 3 4 5 6	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a	02:36 2:36 02:36 02:36
2 3 4 5 6 7 8	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36	02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:36	02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8 9	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:30 Ph.D.s. I have worked with Ph.D.s that I felt were	02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8 9 10	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:10 Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment.	02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8 9 10 11	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02:36 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:: Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. 02:36	02:36 2:36 02:36 02:36 02:36 02:36 36 02:36
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2 3 4 5 6 7 8 9 10 11 12 13 14	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35 Q So when you were defining your person of 02:35 ordinary skill in the art, were you taking into 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02:36 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:36 Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. Q And 02:36 A And I will mention in passing: I know 03:34 M.D.s that are not qualified to make that kind of a	02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35 Q So when you were defining your person of 02:35 ordinary skill in the art, were you taking into 02:35 account the skill that would be necessary to 02:35 evaluate the results? 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02:36 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:36 Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. Q And 02:36 A And I will mention in passing: I know 03:35 M.D.s that are not qualified to make that kind of a judgment, so I don't think it's really whether you have a Ph.D. or an M.D. Yeah. 02:36	02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35 Q So when you were defining your person of 02:35 ordinary skill in the art, were you taking into 02:35 account the skill that would be necessary to 02:35 evaluate the results? 02:35 A Yes. 02:35 Q Okay. And in your view, that would 02:35	it's clinically significant. Right. 02:36 So I think, again, that requires judgment 02:36 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:36 Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. 02:36 A And I will mention in passing: I know 02:36 A And I will mention in passing: I know 03:36 M.D.s that are not qualified to make that kind of a judgment, so I don't think it's really whether you have a Ph.D. or an M.D. Yeah. 02:3 Q Did you, in in determining what the 03:38 skill level is "of a person of ordinary skill," 02:38	02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35 Q So when you were defining your person of 02:35 ordinary skill in the art, were you taking into 02:35 account the skill that would be necessary to 02:35 evaluate the results? 02:35 A Yes. 02:35 Q Okay. And in your view, that would 02:35 require a high level of skill? 02:35	it's clinically significant. Right. So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? O2:36 A Not necessarily. I think I know 02:: Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. Q And 02:36 A And I will mention in passing: I know 04 M.D.s that are not qualified to make that kind of a judgment, so I don't think it's really whether you have a Ph.D. or an M.D. Yeah. Q Did you, in in determining what the 04 skill level is "of a person of ordinary skill," 02:36 evaluate the level of skill of the inventors named	02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	as to "results." A I mean, there's a lot of things that are 02:35 missing from this particular statement. So again, 02:35 you're making some very broad statements. 02:35 You don't specify what the number of 02:35 subjects studied is going to be. You don't discuss 02:35 what your power calculations are. You don't specify 02:35 what you're going to consider significant and 02:35 nonsignificant. So this is I mean, this is sort 02:35 of a very bare-bones description of what what you 02:35 would really need to do to evaluate that. 02:35 Q So when you were defining your person of 02:35 ordinary skill in the art, were you taking into 02:35 account the skill that would be necessary to 02:35 evaluate the results? 02:35 A Yes. 02:35 Q Okay. And in your view, that would 02:35 require a high level of skill? 02:35 A No. In my view, it would require more 02:35	it's clinically significant. Right. So I think, again, that requires judgment 02 about what the overall context in the field is and what a significant improvement would be. Q And would judgments about the clinical significance of the results, that would require a medical degree? 02:36 A Not necessarily. I think I know 02:36 Ph.D.s. I have worked with Ph.D.s that I felt were qualified to make that kind of a judgment. Q And 02:36 A And I will mention in passing: I know 03 A And I will mention in passing: I know 04 M.D.s that are not qualified to make that kind of a judgment, so I don't think it's really whether you have a Ph.D. or an M.D. Yeah. Q Did you, in in determining what the 03 skill level is "of a person of ordinary skill," 02:36 evaluate the level of skill of the inventors named on the patent? 02:36	02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36 02:36
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Page 355
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         I, JAY W. HEINECKE, M.D., do hereby declare
5
    under penalty of perjury that I have read the
    foregoing transcript; that I have made any
7
    corrections as appear noted, in ink, initialed by
    me, or attached hereto; that my testimony as
9
    contained herein, as corrected, is true and correct.
10
        EXECUTED this _____,
11
    (State)
             (City)
12
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14
15
                       JAY W. HEINECKE, M.D.
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Page 356 1 I, MARY J. GOFF, CSR No. 13427, Certified 2 Shorthand Reporter of the State of California, 3 certify; That the foregoing proceedings were taken 5 before me at the time and place herein set forth, at which time the witness declared under penalty of 7 perjury; that the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter 10 transcribed under my direction and supervision; that 11 the foregoing is a full, true, and correct 12 transcript of my shorthand notes so taken and of the 13 testimony so given; 14 That before completion of the deposition, 15 review of the transcript (XX) was () was not 16 requested:) that the witness has failed or (17 refused to approve the transcript. I further certify that I am not financially 18 19 interested in the action, and I am not a relative or 20 employee of any attorney of the parties, nor of any 21 of the parties. 22 I declare under penalty of perjury under the 23 laws of California that the foregoing is true and 24 correct, dated this 30th day of July, 2019. 25 MARY GOFF

Amarin Pharma Inc. et al. v. Hikma Pharmaceuticals USA Inc. et al., No. 2:16-cv-02525-MMD-NJK (D. Nev.)

Deposition of Jay W. Heinecke, M.D., July 17, 2019

I wish to make the following changes, for the following reasons:

PAGE:LINE	CHANGE FROM	CHANGE TO	REASON
10:1	I'm currently provide by	I'm currently a professor	Transcription error
	the	at the	
17:4	somebody at Bud Barner	somebody at Budd	Transcription error
		Larner	
48:19	biochemists in the n-3	biochemists and the	Transcription error
	(indiscernible) positions	omega-3 in the medical	
	in the medical		
68:19-20	It's manifested by the	It's manifested by the	Transcription error
	lack of protein particles	lack of lipoprotein	
		particles	
114:15	For raising LDL-C	For raising LDL-C	Transcription error
	cholesterol	cholesterol?	
114:25	deflecting IDL and LDL.	affecting IDL and LDL.	Transcription error
190:11	there was a whole nother	there was a whole other	Transcription error
	contingent	contingent	
193:2	forward as for as as	forward [delete for – as	Transcription error
	well	<u>- as</u>] as well.	2
197:13-14	study as a	study <u>has</u> a	Transcription error
215:9	buying a gen	buying a generic	Transcription error
227:1	certainly an HDL	certainly an HDL expert,	Transcription error
229:2-3	at hand here, whereas	at hand here, whereas	Transcription error
	DHA did not.	EPA did not.	
252:8	has a value of 233 with	has a value of 300 with	Conform to facts
261:25	and what you should	and what you should	Transcription error
	synch.	use.	
287:22	BRUNNEL [sic]	BRUNZZEL	Transcription error
296:9	for example, is plat	for example, is	Transcription error
		plasmapheresis	
297:14	get erupted xanthomas	get eruptive xanthomas	Transcription error
333:9	of "whoa" where	of woes where	Transcription error

PAGE:LINE	CHANGE FROM	CHANGE TO	REASON
343:21	synth synth statin-	simvastatin-treated	Transcription error
	treated patients	patients	
347:8	increase LD actually	increase <u>LDL</u> -	Transcription error
		cholesterol actually	

I, Jay W. Heinecke, do hereby certify that I have read the transcript of my deposition and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance noted above.

Dated: Aug 14, 2019

Jay W. Heinecke